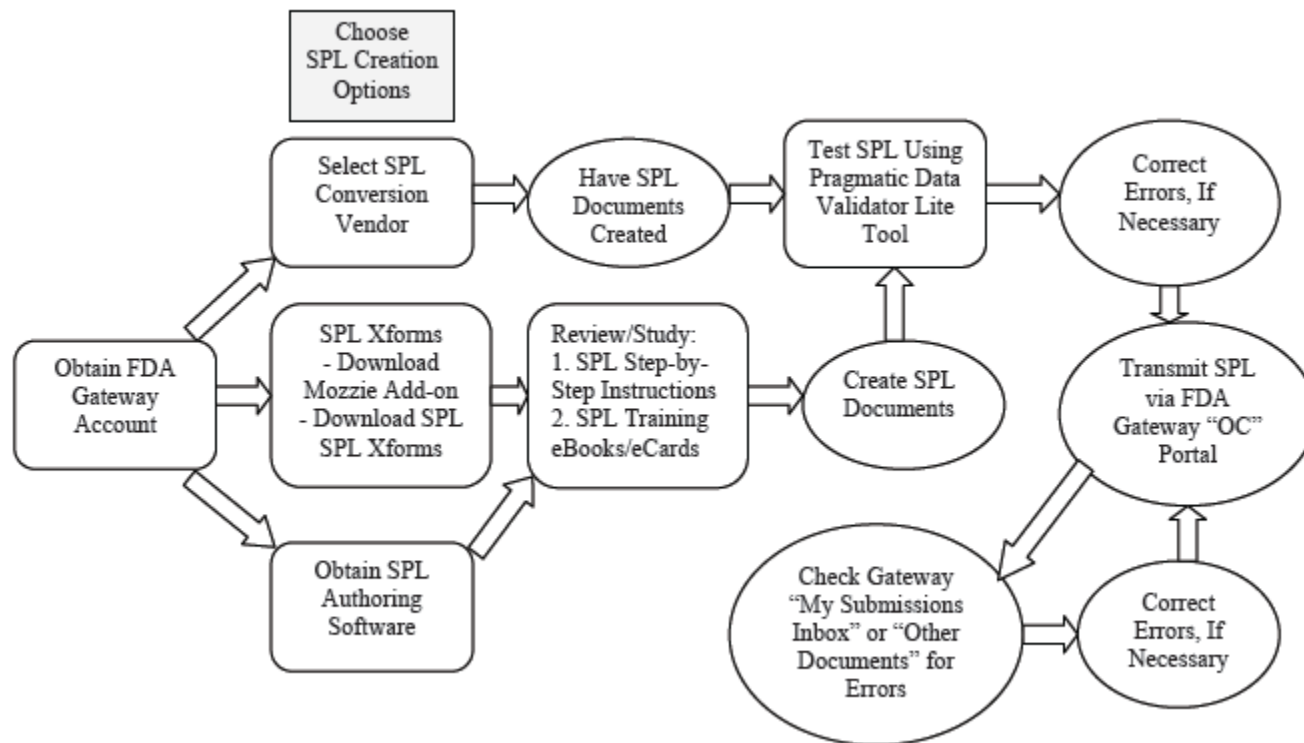


Creating a Content of Labeling/ Drug Listing SPL Document – Rx Drug Products

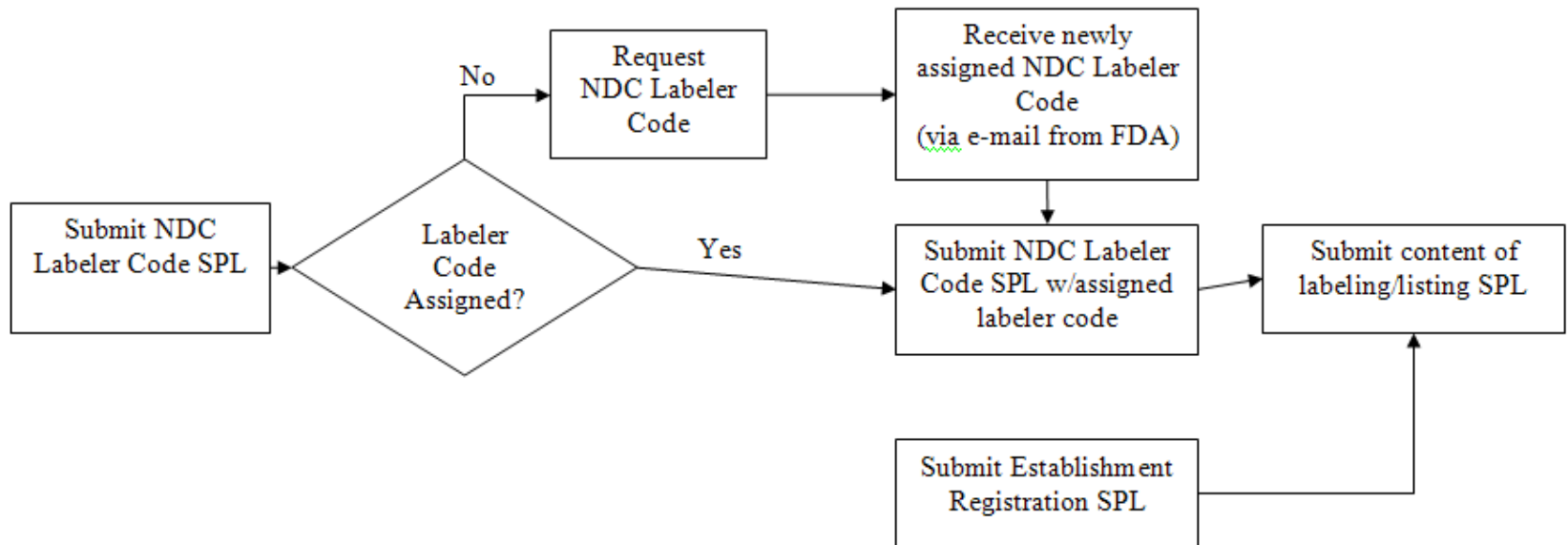
Lonnie Smith
Policy Analyst
Structured Product Labeling Team
FDA Data Standards Council



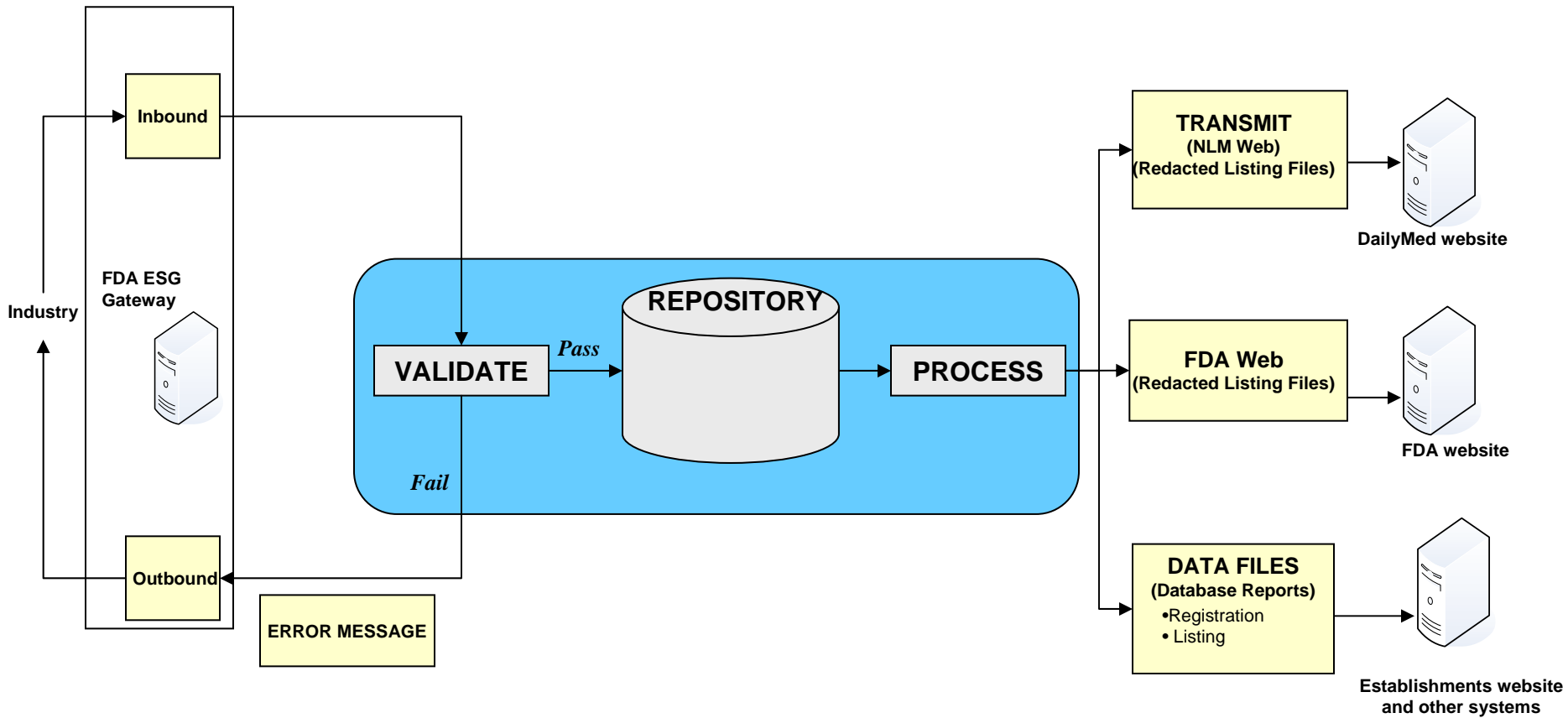
“Road Map” Creation & Submission



SPL Submission Process



eLIST



Validation Error Notifications

- Transmitted via FDA Gateway to submitter
- Transmissions occur within 36 hours (business days)
- In the form of a 2nd or 3rd acknowledgment
 - 2nd acknowledgment – system-generated message
 - 3rd acknowledgment – manually generated message with additional notes
- No 2nd or 3rd acknowledgment within 24 hours usually denotes that submission was accepted

Technical Terms Glossary

Term	Definition
Core ID	A unique identifier which the FDA ESG assigns to every submission and uses for reference purposes
Document Root ID	Globally Unique Identifier (GUID) and is unique for each version of the document. Also referred as “root ID,” “ID,” “document ID,” or “document root ID.”
Effective Time	Provides a date reference to the SPL document version or a section including the year, month and day as yyyyymmdd.
GUID	Globally Unique Identifier (used as the SPL document root ID, setID, or section IDs)
SetID	Globally Unique Identifier (GUID) and is a unique identifier for the document that remains constant through all versions/revisions of the document.
UUID	Universal Unique Identifier (UUID) Synonymous w/GUID (see definition for GUID)
Version Number	Integer greater than zero that provides a sequence to the versions of the document.

Product Data Elements

- Product
 - Product names
 - NDC Product Code
 - Source NDC Product Code (original manufacturer) – Repacked/Relabeled
- Description
 - Ingredients
 - Strength
 - Dosage form
 - Route of administration
 - Controlled substance code
 - Appearance
- How supplied
 - Packaged product

Only terms in the controlled terminology are allowed.

Strength of Ingredient

- SPL R4 documents will allow companies to **designate strength based on the active ingredient, active moiety or a reference drug.**

Example of non-solid dosage form

Numerator: **10 mg**

Denominator: **1 mL**

Example of solid dosage form

Numerator: **10 mg**

Denominator: **None**

Strength cont...

Product	Numerator unit	Denominator unit
Oral solid	Weight	Each
Oral liquid	Weight	Volume
Oral powder for reconstitution with a known volume	Weight	Volume
Oral powder for reconstitution with a variable volume	Weight	Each
Suppository	Weight	Each
Injection liquid	Weight	Volume
Injection powder for reconstitution with a known volume	Weight	Volume
Injection powder for reconstitution with a variable volume	Weight	Each
Inhaler powder	Weight	Each
Inhaler liquid	Volume	Each
Inhaler blister	Weight	Each
Topical cream or ointment	Weight	Weight
Topical gel or lotion	Weight	Volume
Transdermal patch	Weight	Time
Bulk liquid	Weight	Volume
Bulk solid	Weight	Weight

PROPRIETARY NAME - name(s) of active ingredient(s) dosage form
Labeler

SPL Release Four Drug Listing Data Elements (Example w/Nonsolid Oral Dosage Form) - Revised Stylesheet

PROPRIETARY NAME			
name(s) of active ingredient(s) dosage form			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	NDC Product Code (Source)	0001-0001
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
name(s) of active ingredient(s) (name of active moiety number 1 and name of active moiety number 2)	name(s) of active ingredient(s)	50 mg	
Inactive Ingredients			
Ingredient Name	Strength		
name of inactive ingredient			
Product Characteristics			
Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			
Packaging			
#	NDC	Package Description	Multilevel Packaging
1	0001-0001-02	5 mL In 1 VIAL	None

Drug Listing/CoL SPL Document

MIRACLE XR

good drug tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	NDC Product Code (Source)	44444-333
Route of Administration	ORAL	DEA Schedule	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Good Drug (active moiety)	Good Drug	25 mg

Inactive Ingredients

Ingredient Name	Strength
Inactive ingredient one	

Product Characteristics

Color	yellow (yellow-orange)	Score	2 pieces
Shape	ROUND (ROUND)	Size	18mm
Flavor	CITRUS (citrus-flavored)	Imprint Code	AC;25;mg
Contains			

Packaging

#	NDC	Package Description	Multilevel Packaging
1	44444-333-10	1 BOTTLE In 1 CARTON	contains a BOTTLE (44444-333-50)
1	44444-333-50	50 TABLET In 1 BOTTLE	This package is contained within the CARTON (44444-333-10)

Marketing Category

- Select the appropriate marketing category for the drug product.

Marketing Information	
Marketing Category	
NDA	

Application or Citation Number

- Application numbers include the character application abbreviation and the numbers without spaces or dashes (e.g., NDA123456). Monograph citations include the number of the regulatory part (e.g., part234). (DO NOT enter “000000”)

	Application Number or Monograph Citation
	NDA000000

Marketing Status & Date

- The marketing status describes the activity of the product
- SPL file is removed from the public repository. The expiration date of the last lot released to the marketplace provides an estimate of the date when the SPL file is removed.

Marketing Status & Dates

- Status of product
 - **Active:** on the market
 - **Completed:** when marketing is done the drug is no longer going to be available on the market.
 - Active or completed timestamp: effectiveTime value.
- Low value
 - Time on the market
 - Determines release of CoL/Listing SPL to public
- High value
 - Time off the market (e.g. the expiration date of the last lot released to the market.)

Marketing Start Date	Marketing End Date
01/24/2005	

Marketing Status & Dates

- Status of product
 - **Active:** on the market
 - **Completed:** when marketing is done the drug is no longer going to be available on the market.
 - Active or completed timestamp: effectiveTime value.
- Low value
 - Time on the market
 - Determines release of CoL/Listing SPL to public
- High value
 - Time off the market (e.g. the expiration date of the last lot released to the market.)

Marketing Start Date	Marketing End Date
01/24/2005	

Labeler/Establishment Data Elements

Labeler - Labeler name here (labeler DUNS Number here)

Establishment

Name	Address	ID/FEI	Operations
Establishment name here		Establishment DUNS Number here	manufacture

Establishment

Name	Address	ID/FEI	Operations
Establishment name 2 here		establishment DUNS Number here	manufacture

Revised: 02/2009

Labeler name here

Content of Labeling

- Sections and Subsections
- Symbols and Characters
- Font Effects
- Footnotes
- Lists
- Tables
- Images

Drug Listing/CoL SPL Document

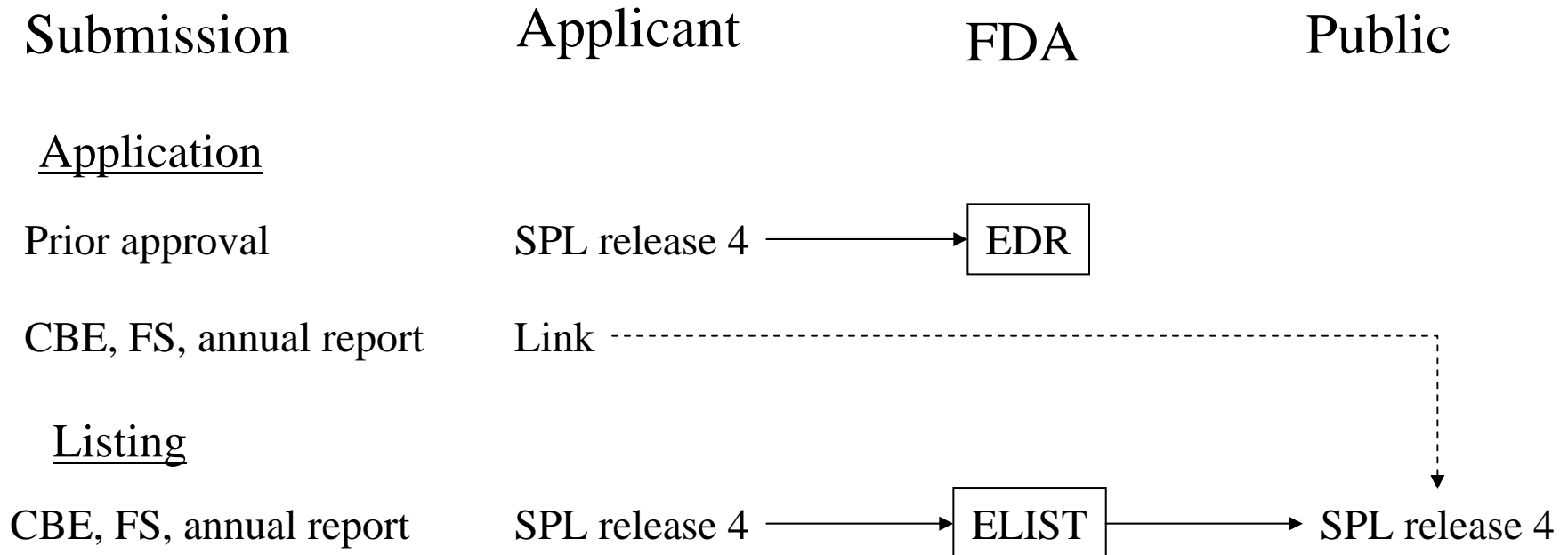
MIRACLE XR - good drug tablet
Acme Pharmaceuticals, Inc

Miracle XR

Description

Description text placeholder

Application Product Listing in Electronic Format with Link to Posted SPL file (when file submitted via eListing Process)



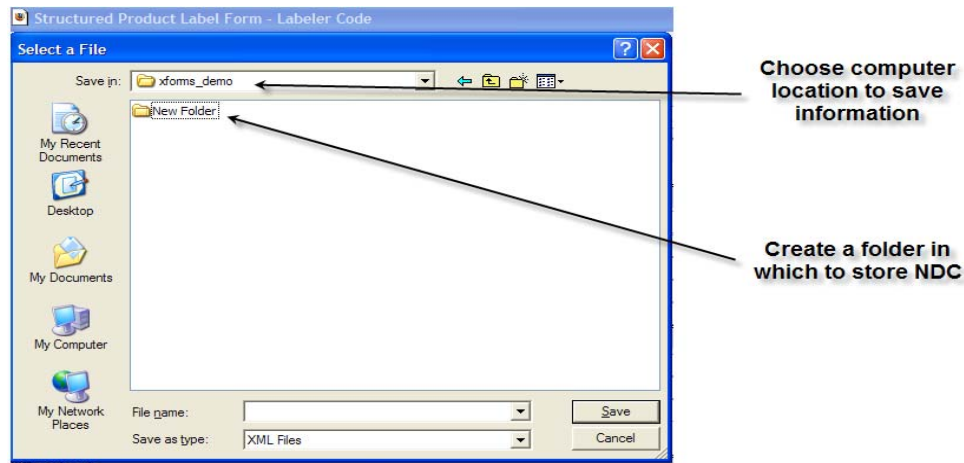
Referencing “Application Product” SPL

- Referencing the identical content of labeling submitted during listing process
- Include a statement and hyperlink in your application submission
- (e.g., “We have submitted the SPL file with drug listing; it can be found at the following location <http://www.accessdata.fda.gov/spl/data/> [*insert your SPL document id root here/insert SPL document id root here*].xml”]

Updating SPL Document Tracking Information

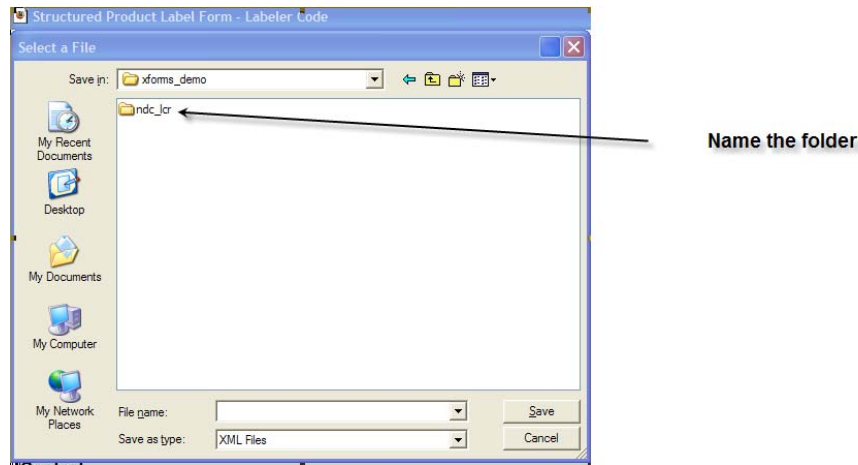
- **Use**
 - **new** id root
 - **new** version number
 - original setId
 - appropriate effective time
- **Misplaced SetID/SPL File**
 - E-mail core ID to spl@fda.hhs.gov
 - Include contact person's name and DUNS Number which were included in original SPL file

Creating the Submission Folder



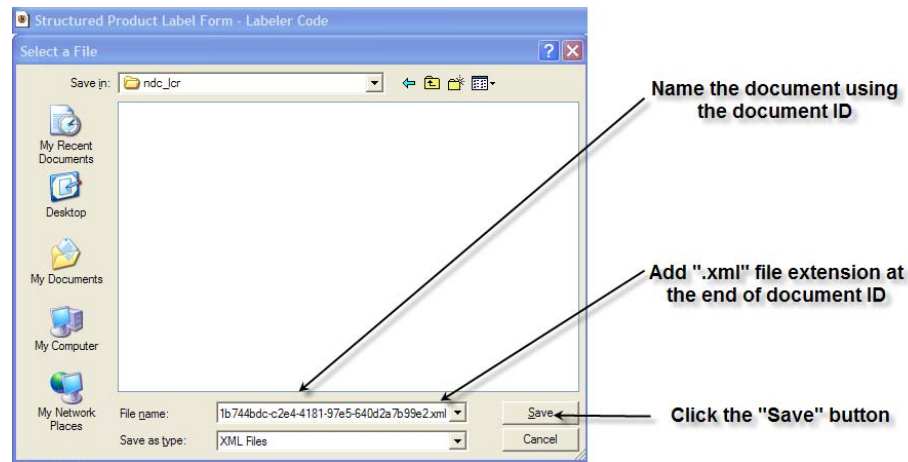
- Choose computer location in which to store folder to contain the SPL file.
- Create a folder in which to store the NDC Labeler Code SPL file.

Naming the Submission Folder



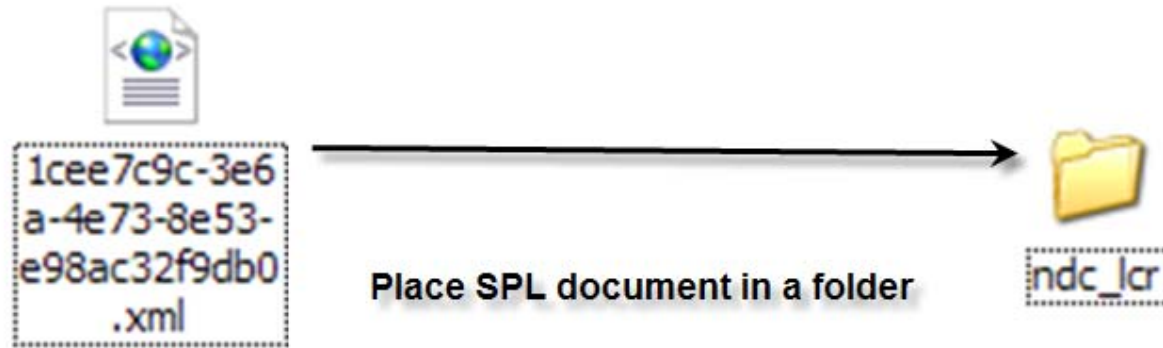
- There is no folder naming convention
- However, we recommend not using symbols in the name of the folder.

Naming the SPL File



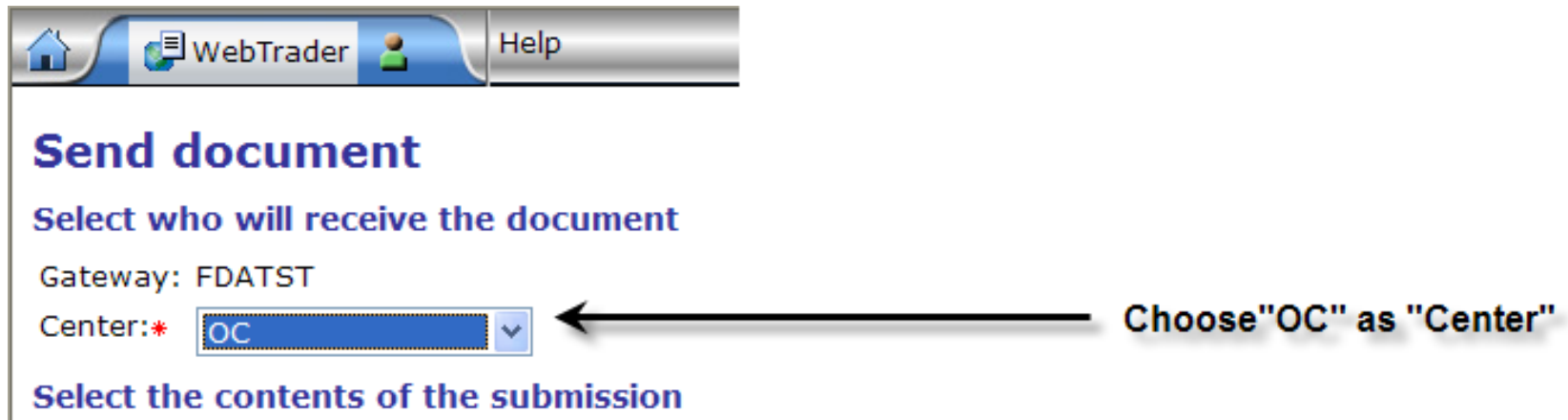
- Use the **document ID** (GUID) as the document file name
- Use “.xml” as the file extension
- Choose “Save” button
- If you do not follow these steps your SPL will **FAIL** validation.

Place SPL File in Folder



- Place SPL document in a folder.
- Ensure that SPL file name is document root ID with “.xml” as file name extension.
- Only **ONE** SPL document per folder. If applicable, image files (jpeg) may accompany listing SPL document in folder.

Choosing “Center”



WebTrader Help

Send document

Select who will receive the document

Gateway: FDATST

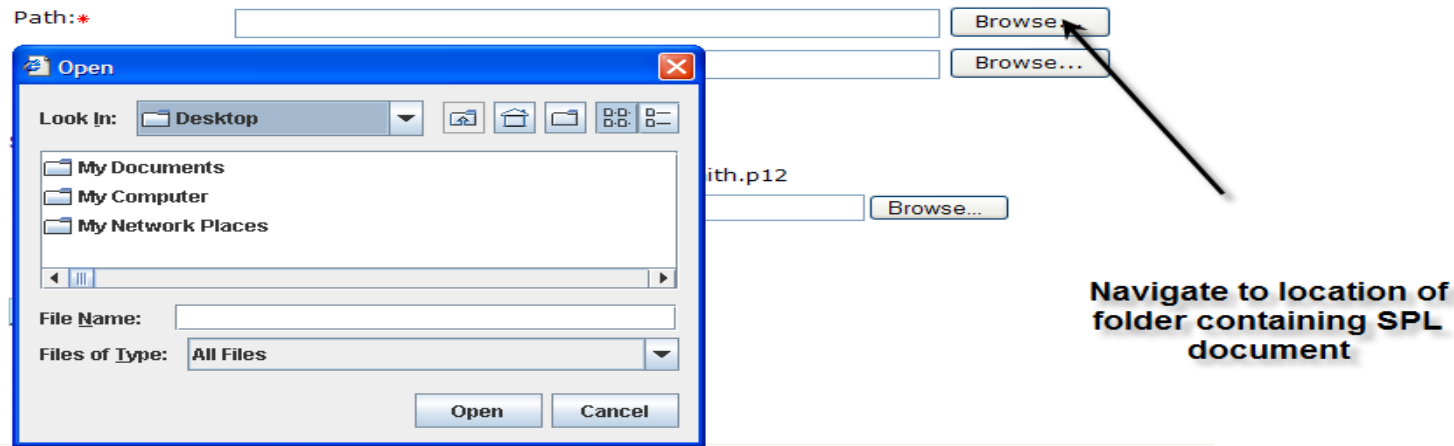
Center: * ▼

Select the contents of the submission

Choose "OC" as "Center"

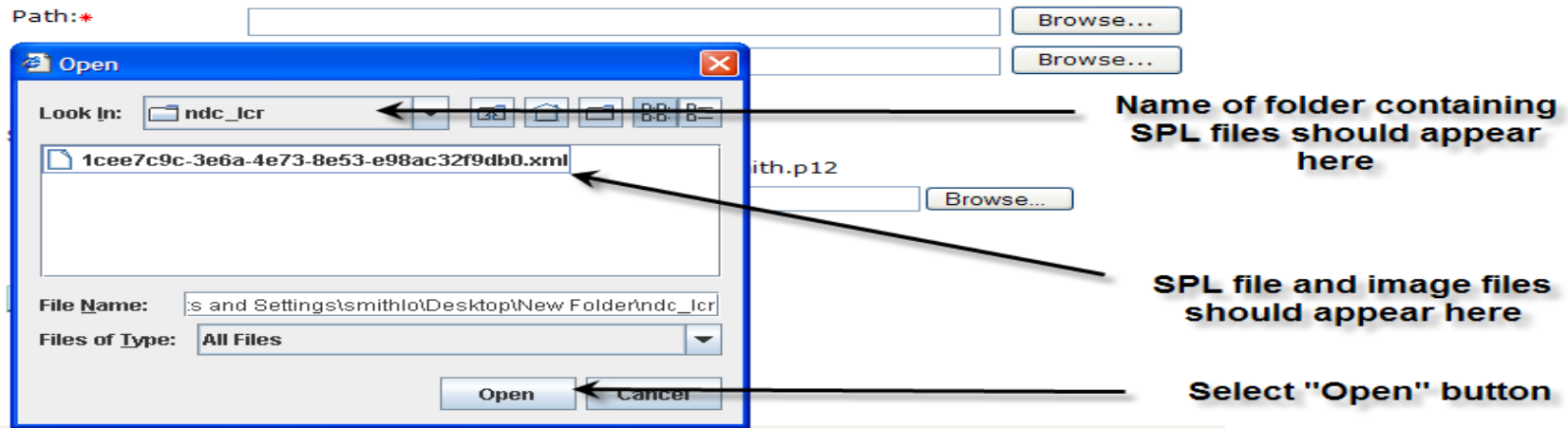
- Select “OC” as the FDA Gateway “center.”
- NDC Labeler Code, Establishment Registration, & Content of Labeling/Listing SPL documents submitted for the purpose of registering a drug establishment and listing a drug product should be sent via “OC.”

Navigate to Folder w/SPL



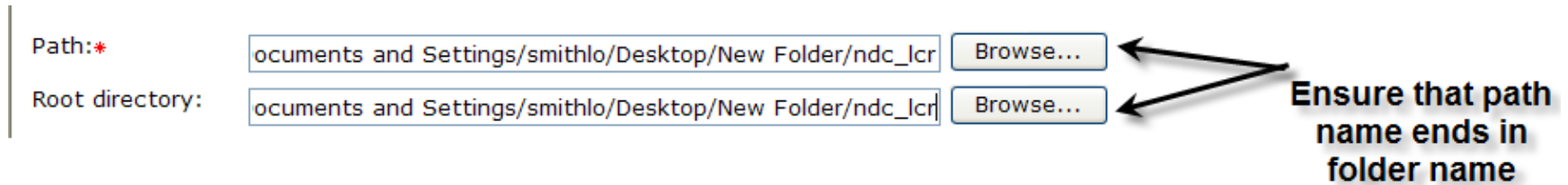
- Click browse button to navigate to location of folder containing SPL file (and, if applicable, associated image files.)

Selecting SPL Submission



- Ensure that you are sending folder.
- Check to be sure that you are not sending a folder within a folder
- Select "Open" to continue.

Checking Path Name



- Ensure that path name ends in the name of folder which contains the SPL document and JPEG files.
- If path ends in file name, then you are only sending the file and not the folder containing files.

Selecting Submission Type

Submission type: *  ← Select submission type "SPL"

- Use drop-down menu to select submission type “SPL.”
- If submission type “SPL” does not appear, you have chosen the wrong center and not “OC.”

Verify or Select Digital Certificate



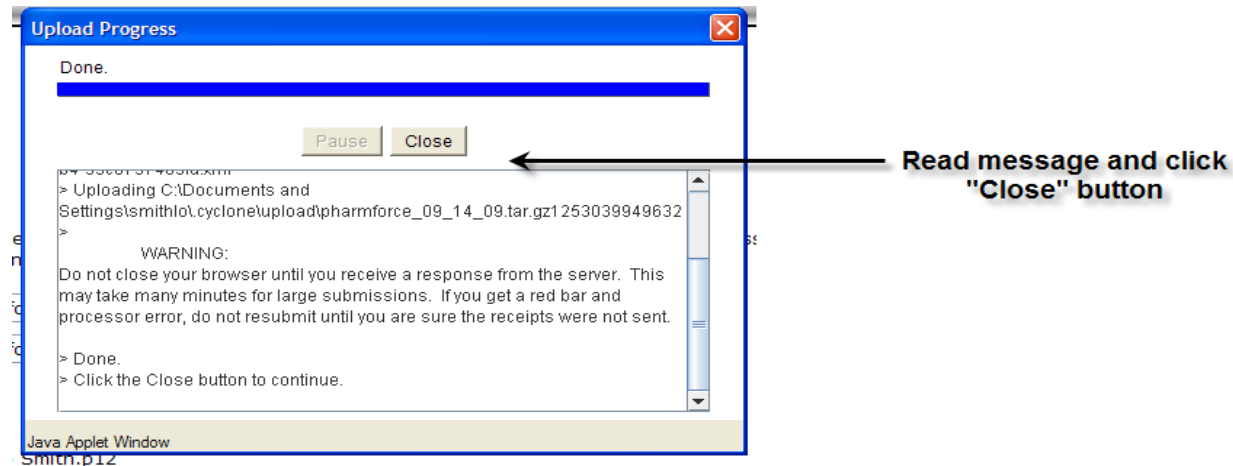
- Verify that your digital certificate is being used.
- Or browse to the location of the digital certificate on your computer.

Sending the Submission



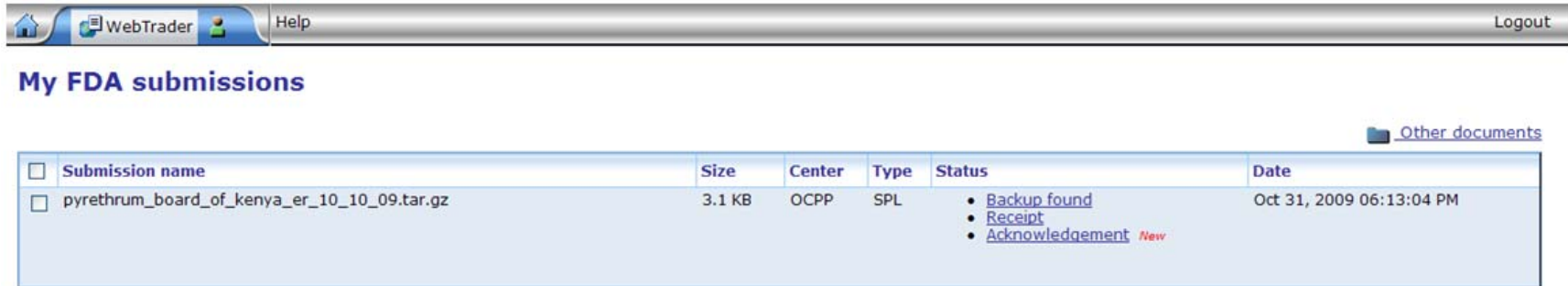
- Select the “Send” button.
- Enter your password to unlock signing certificate.
- Select the “OK” button

Completing Gateway Submission



- Read message in prompt window
- Select "Close" button

Log onto FDA Gateway




The screenshot shows the FDA Gateway WebTrader interface. At the top is a navigation bar with a home icon, 'WebTrader' text, a user icon, 'Help', and a 'Logout' link. Below this is a section titled 'My FDA submissions'. To the right of this section is a link for 'Other documents'. The main content is a table with columns: Submission name, Size, Center, Type, Status, and Date. One submission is listed: 'pyrethrum_board_of_kenya_er_10_10_09.tar.gz' with a size of 3.1 KB, center OCPP, and type SPL. The status column for this submission contains a bulleted list of links: 'Backup found', 'Receipt', and 'Acknowledgement' (which is marked as 'New' in red). The date is 'Oct 31, 2009 06:13:04 PM'.

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	pyrethrum_board_of_kenya_er_10_10_09.tar.gz	3.1 KB	OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM

- Log onto the FDA Gateway
- Select the “My FDA submissions” or “Other documents” hyperlinks

Selecting the File w/Core ID

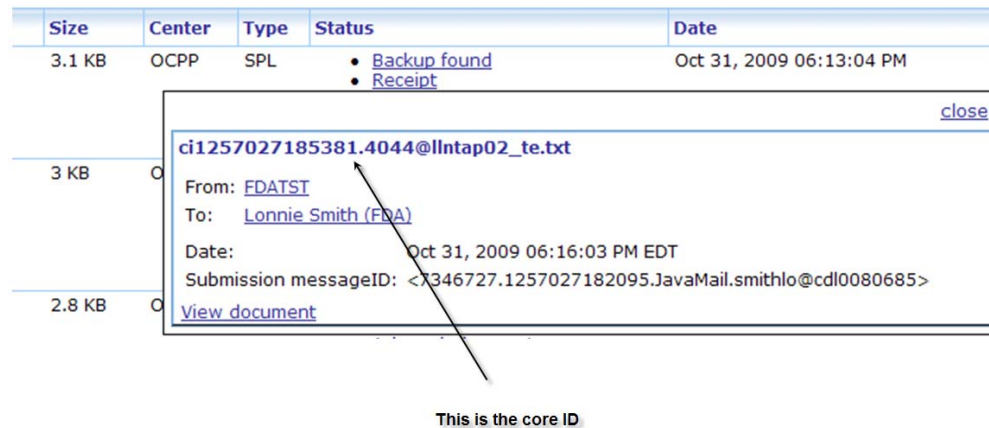
Center	Type	Status	Date
OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM



Click the "Acknowledgment" hyperlink


- The **first** "Acknowledgment" link should take you to window with core ID.


Finding the Core ID



- After selecting the “Acknowledgment” hyperlink, window should display.
- Core ID is located in top left of “Acknowledgment” window. (.txt is not part of the actual core ID)
- Use this core ID to reference submission when communicating with FDA about status or issue with SPL document.


Finding Error Messages

 WebTrader

 Help

Logout

My FDA submissions

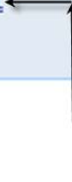
 [Other documents](#)

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	wellness_center.tar.gz	3 KB	OCP	SPL	<ul style="list-style-type: none">Backup foundReceiptAcknowledgementAcknowledgement <i>New</i>	Oct 31, 2009 03:09:46 PM

- Logon to the FDA Gateway
- Select the “My FDA submissions” or “Other Documents” hyperlinks

Selecting Error Message

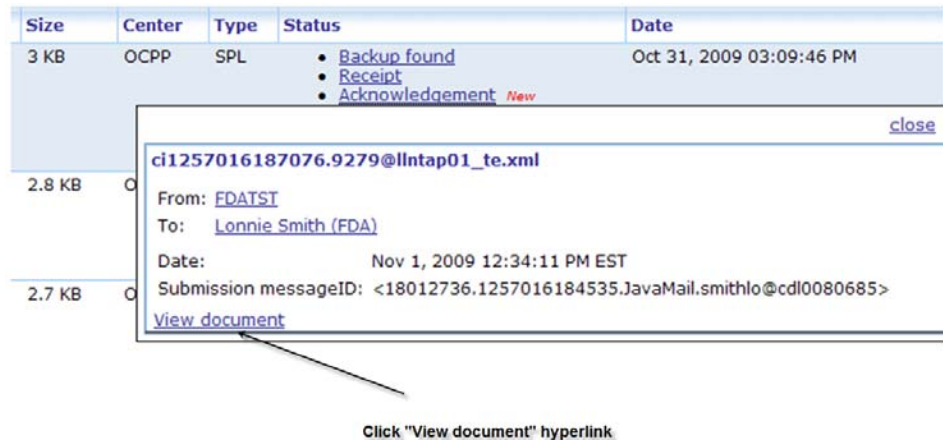
Size	Center	Type	Status	Date
3 KB	OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement• Acknowledgement New	Oct 31, 2009 03:09:46 PM



Click on second (or third) "Acknowledgment" hyperlink

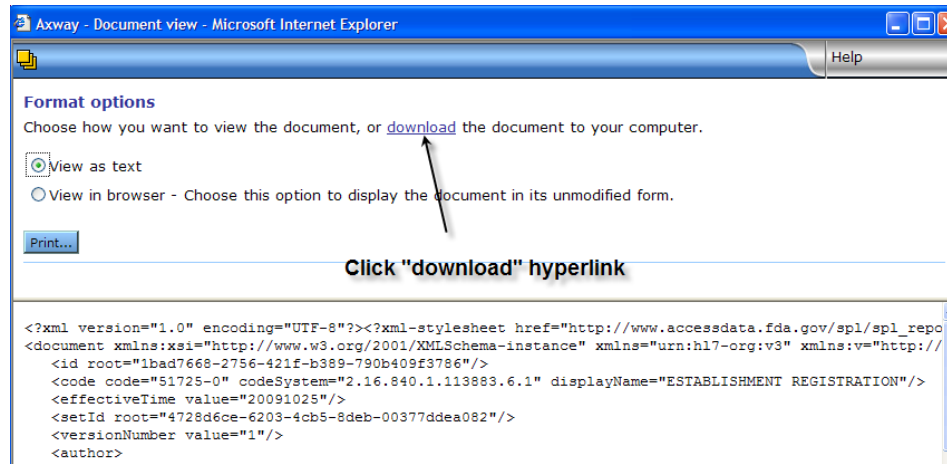
- Receipt of a second or third “Acknowledgment” hyperlink is indicative that there is an error with your submission.
- Click on second (and third, if available) “Acknowledgment” hyperlink.

Opening Error Messages



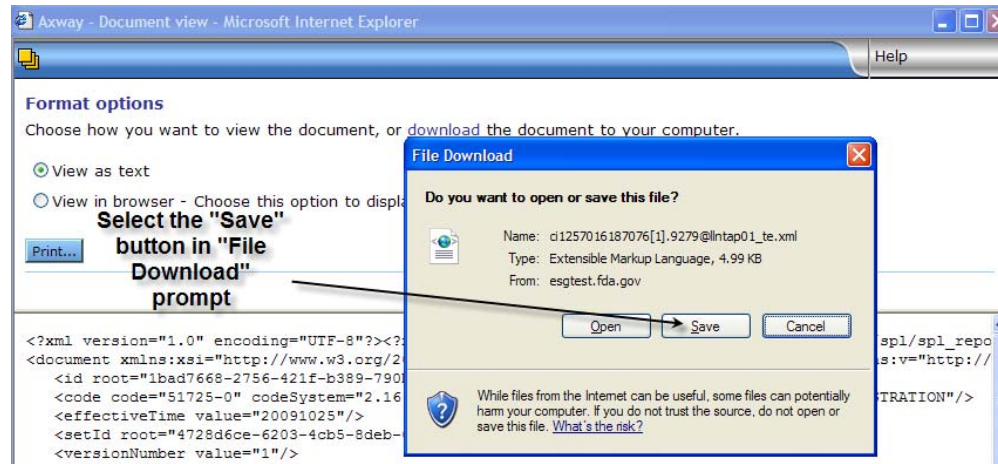
- Click the “View Document” located in the bottom left corner of Acknowledgment prompt window.

Downloading Error Message



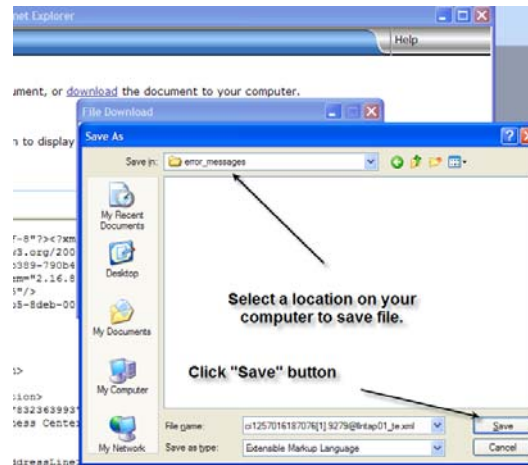
- Select the “download” hyperlink to download the error message to location on computer

Saving the Error Message Document



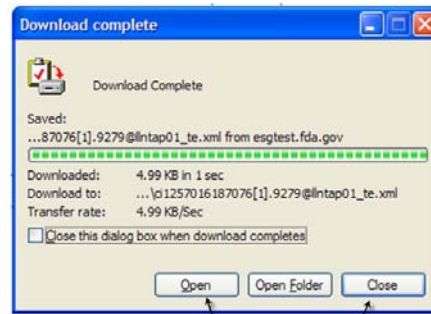
- Click the “Save” button in the “File Download” window prompt.

Saving the Error Message Document cont...



- Navigate to preferred location on your computer in which to store the error message.
- Click the “Save” button to save message in preferred location.

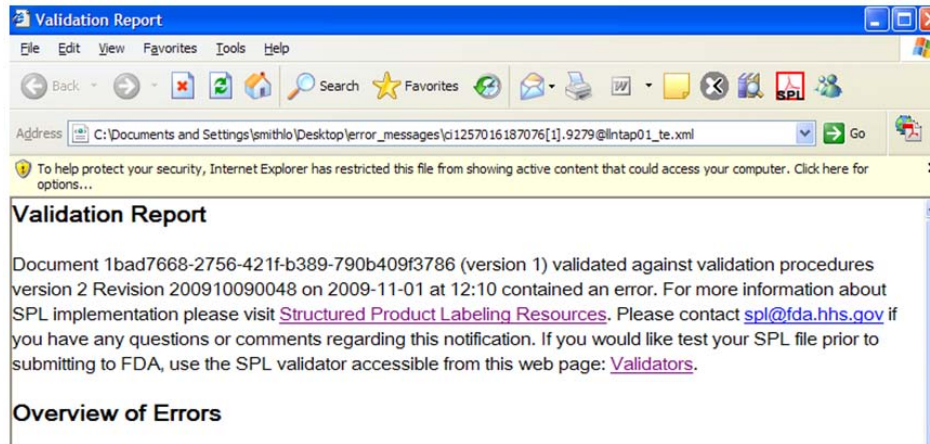
Completing Download



Select "Open" or "Close" buttons

- You can open the message from the "Download complete" window prompt
- You can also close the window and directly open from location on your computer where message was stored.

Review the Error Message



- Review the error message

Configuring PC to View Error Message

- If you are experiencing technical difficulties resulting in your inability to view the error message you have downloaded, we recommend that you follow these steps for Internet Explorer
 - Click the "Tools" menu and select "Internet Options".
 - Click the "Security" tab.
 - Click the "Custom level" button.
 - Scroll down to the "Miscellaneous" section.
 - Enable the "Access data sources across domains".
 - Click "OK" to accept the update.
 - Click "OK" to close the security dialog.

Test Your SPL R4 Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>
- NOTE
 - This validator tool is **NOT** connected to FDA database.
 - This tool assist you in detection of **90 – 95%** of technical errors in SPL documents.

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov URL. Below this is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories: Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates' link with an arrow pointing to it. Below this is a paragraph explaining the council's role in coordinating data standards. At the bottom of the main content area is a link for 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

Product Data Elements

These highlights do not include all the information needed to use Cymbalta safely and effective - Windows Internet Explorer

C:\Documents and Settings\smithlo\Desktop\w_location\2011_spl_training_sessions\source_files\2222222-1111-f212-5921-59381df221e1.xml

File Edit View Favorites Tools Help

Product Data Elements

PROPRIETARY NAME PROPRIETARY NAME SUFFIX (IF NECESSARY)

active ingredient name(s) here dosage form

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:1111-2222
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
active ingredient name (active moiety)	active moiety	20 mg

Inactive Ingredients	
Ingredient Name	Strength
inactive ingredient	
inactive ingredient	

Product Characteristics			
Color	green (green)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	20;mg
Contains			

Done

start

My Computer 100%

10:00 AM

Application Number

- Application numbers include the character application abbreviation and the numbers without spaces or dashes (e.g., NDA123456).
- Unapproved drugs – Use the “unapproved drug other” marketing category – DO NOT enter an application number

Content of labeling

- Sections
- Subsections
- Hyperlinks (only if applicable)
- Highlights text (labels in Physician Labeling Rule format)

Highlights Title

- If there are highlights (PLR format), then the title for the SPL file includes the text string (without quotation marks): “These highlights do not include all the information needed to use” “see full prescribing information for” and “Initial U.S. Approval”

Adverse Reactions Section (PLR Format Only)

- An excerpt in the adverse reactions section (34084-4) includes the statement "to report suspected adverse reactions" and "1-800-FDA-1088" (different telephone numbers for documents of type 53404-0 – "Vaccine Label").
- For PLR format labels

SPL Submission for Application Product Listing in Electronic Format

Submission

Applicant

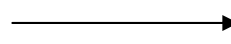
FDA

Public

Application

Prior approval

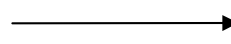
SPL release 4



EDR

CBE, FS, annual report

SPL release 4

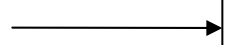


EDR

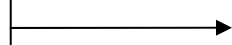
Listing

CBE, FS, annual report

SPL release 4

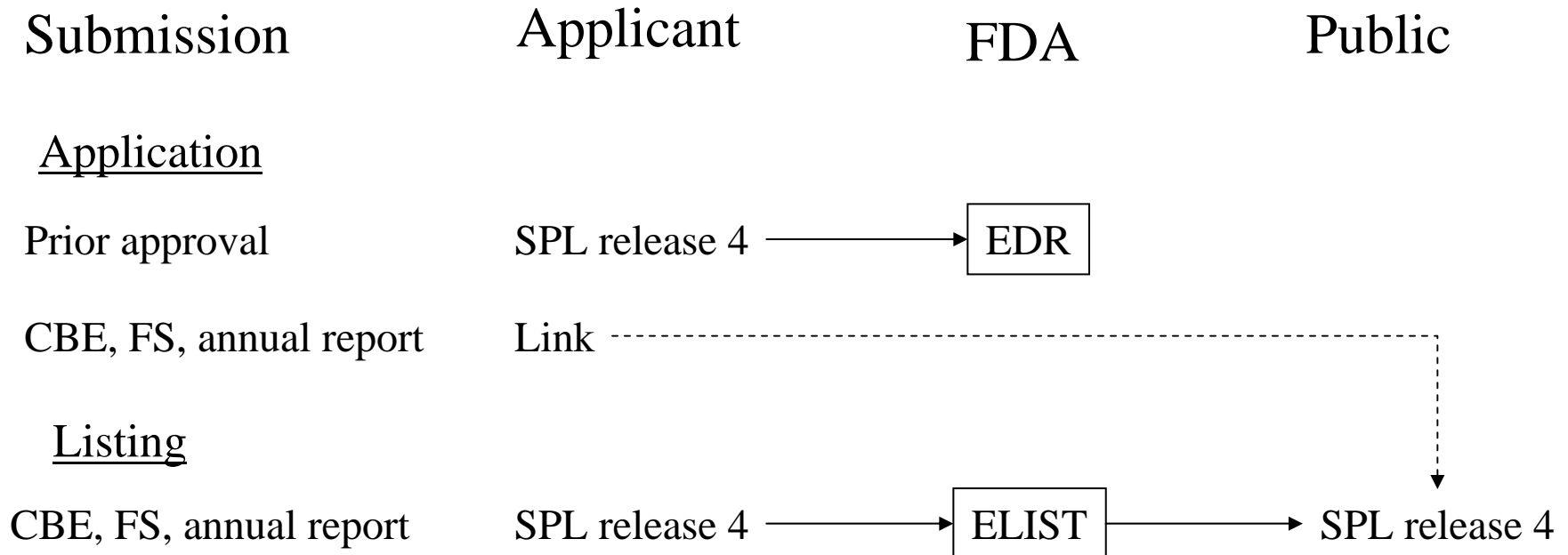


ELIST



SPL release 4

Application Product Listing in Electronic Format with Link to Posted SPL file (when file submitted via eListing Process)



Referencing “Application Product” SPL

- Referencing the identical content of labeling submitted during listing process
- Include a statement and hyperlink in your application submission
- (e.g., “We have submitted the SPL file with drug listing; it can be found at the following location <http://www.accessdata.fda.gov/spl/data/> [*insert your SPL document id root here/insert SPL document id root here*].xml”]

SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)

Components of Rx SPL File

- Content of labeling
- Carton or container label(s)
- Product Data Elements (drug listing)